delivery to any of the hand-held injection devices **40, 40', 40" , 40"' or 40""**.--

REMARKS

An old Figure 13 was inadvertently filed. Newly submitted Figure 13 is supported in the specification at page 3, line 11, page 15, line 2- 12, *inter alia*. The Hall effect switch was called out as reference **31** in old Figure 13 and is accurately drawn in newly submitted Figure 13.

The manufacturing source of the Hall effect switch has been added. Additionally, typographical errors were corrected. In a few cases, the specification referred to "any of the hand-held devices" and omitted a reference number. This has been corrected. No new matter has been added.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Version with markings to show changes made.**"

Applicant respectfully requests that this Preliminary Amendment be entered into the record.

Respectfully submitted,

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FIRST CLASS MAIL CERTIFICATION

I certify that this:

Preliminary Amendment, certificate of first class mailing, return receipt postcard, and

any other papers mentioned as included herein, for the above-identified patent application is being mailed by First Class Mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231, this 2nd day of October 2001.

Janet P. Schafer
Patent Attorney

Version with markings to show changes made

In the specification:

The paragraph beginning at line 1 of page 3 has been amended as follows:

Manually depressing a trigger on the hand-held injection device of this delivery system, in conjunction with inserting a needle into the subject body, actuates [actuation of] the pump [causes] causing fluid to flow through the hollow needle accomplishing an injection. An emergency stop button is provided [if] in case an error is made,[e.x.] ex., the needle goes through the ear, or through the ear and into the user's hand, to prevent injection of a medicament into the user. This is an important deterrent to self-injection. An additional embodiment provides a safety interlock member which must be depressed to the needle hub to close the electrical switch which in turn actuates the pump causing fluid flow through the hollow needle only when the needle is fully injected actuates an injection. This safety interlock is adjacent to the needle and positioned to extend to the length of the needle. This safety interlock is then depressed to the point adjacent to the needle hub as the needle is inserted. At this juncture, an internal extended rod from the safety interlock closes the electrical circuit by means of a Hall-effect switch. This, in turn, actuates the pump to cause fluid flow through the needle. This feature also deters accidental self-injection. Injection cannot take place until the needle is fully inserted, thus enabling the operator to withdraw an accidental stab prior to injection taking place. The goal of both of the systems is operator safety. Self-injection is a very serious accident among vaccinating crews.

Paragraph beginning at line 19 of page 3 has been amended as follows:

The delivery system is powered by a compact, rechargeable 12-volt battery or 110 volt AC/12 volt DC converter, although other electrical means could be used, for sustained operation reducing fatigue and the likelihood of repetitive stress injury to the operator.

Paragraph beginning at line 26 of page 5 has been amended as follows:

Turning now to the drawings, in which like reference characters refer to corresponding elements throughout the several views, **Fig. 1** illustrates an electrically powered automatic veterinary medicament delivery system, shown generally at **20**. System **20** is housed in a container such as a back pack and includes a hand-held unit **40** in fluid communication, by means of conduit tubing tubing **78**, with a medicament container **70**. A first embodiment hand-held unit **40,** single needle **56**, no dye means, is especially for use in injection of a medicament into the ear of a bovine. All of the hand-held units **40** have a generally cylindrical shape with a flattened surface **41** on which ,[*in*] in embodiments one through three, are mounted both a trigger **42** and an emergency stop **44** button. The fourth embodiment also has a trigger but no emergency stop. Also shown are a green LCD **48**, which lights to indicate an injection is in progress, and a red LCD **50** which lights to indicate that the medicament level is low. The "function" key pad **108** is touched on the control unit **110** to set the anticipated number of total count so that the low medicament bottle LCD lights up at the appropriate time, ex. when 90% of the doses have been given. Head lamp **46** is used to illuminate the area of injection, as well as an optional dye pad **172** along with the needle mount **58,** in actual use, a Luer lock, all mounted on a proximal surface **22** of the hand-held unit **40'''**. Entering this distal end **24** of hand-held unit **40'''** is tubing **82** containing medicament **84**, dye **86** and electrical power cords **88**. All of the various hand-held unit embodiments **40, 40', 40", [&] 40''' & 40''",** look and work similarly. A pump **100**, which sits atop a control unit **110**, sucks up the medicament from within medicament container **70** through tubing **80** and forces the fluid medicament from pump **100** exiting through tubing **82** and continuing through conduit tubing **78** for delivery by the hand-held unit **40** through a hollow needle **56**. The control unit **110** utilizes an electronic dosage control **130**, shown in detail in **Fig.7,** to deliver a predetermined precise amount of medicament upon injection. Additionally, the electronic dosage control **130** provides means of changing the dosage of these predetermined precise amounts of medicament. Control unit **110** also provides optional marking means. Marking dye, in an optional embodiment shown at **Figs. 2,3,& 5**, is delivered through dye

means, such as by an applicator pad **172,** simultaneously with injection of the medicament, marking the individual poultry, porcine, ovine or other animal injected. Control unit **110** function key pad **108** has an on/off control of dye means. Control unit **110** also provides for counting the number of injections made.

Paragraph beginning at line 27 of page 6 has been amended as follows:

In all of the disclosed embodiments, fluid from more than one medicament container **70** can be injected simultaneously through their respective tubing **80**, the medicaments forced by the pump **100,** through an optional mixing tube **190**, shown in detail in **Fig. 10**, intermixing the two medicaments prior to their being injected through the selected hand-held unit **40, 40', 40", 40"'or 40"".** Additionally, in all of the embodiments, fluid from more than one medicament container **70, 70'** can be injected simultaneously. Where different dosages are needed, two control units **110, 110'** with the associated pumps **100, 100'** can be connected up to a single hand-held unit **40, 40', 40" 40"', or 40""** for simultaneous injection, either after mixing the medicaments and injected through hand-held unit **40 40"** and **40"'**, or when the medicaments cannot be mixed for whatever reason, by injecting simultaneously through two needles through hand-held unit **40'** as shown in **Fig. 4**. Once the requirements are determined, which medicaments are to be injected, can they be mixed, if not, are they administered at the same dosage, the appropriate hand-held unit **40, 40', or 40"** is selected and electronically connected to control unit **110** by the Amp connector **94**, attached to the end of conduit tubing **78** and in fluid communication by means of a quick connect fluid connector **196** at the end of each tubing **82, 76**,. If the medicaments may be mixed, the mixing tube **190** must be attached to the tubing **82** by quick connect fluid couplers **196**. Quick connect fluid couplers **196** are also mounted on pump**100** to attach tubing **80** to medicament container **70** . If more than one pump is needed but the medicament to be administered can be given at the same dosage, then a two pump system **100, 100'**, such as shown in **Fig. 8**, is used. [Either hand-held] Hand-held unit **40,** [or] **40' or 40"'** may be used. When the medicament to be administered is not of the same dosage, and cannot be mixed, then two control units **110, 110'** must be used, such as shown in **Fig. 9,** then hand-held unit **40"** is

selected and connected to both control units **110,110'** by means of conduit tubings **78, 78'**. A nine-pin amp connector **94** connects the electronic control unit **110** to any of the hand-held units **40**. A four-pin amp connector **122** connects the electronic control unit **110** to the dye pump. Another four-pin amp connector **124** connects the control unit **110** to the battery **126**. These different types of amp connectors protect against accidental connection of the wrong device to the outlet at the control unit **110.**

Paragraph beginning at line 16 of page 9 has been amended as follows:

Fig. 5 is an end view of a fourth embodiment hand-held unit **40"'** which has a pistol grip **30**. In this embodiment, the generally cylindrically shaped hand-held unit **40"'** is basically turned upside down so that the flattened surface is on the ventral side. The trigger **42** is mounted on the front surface of the pistol grip **30** for convenience of the user. This embodiment has the same elements on the proximal surface **22**, namely a needle mount **58,** a hollow needle **56,** an optional dye means **170**, with associated dye tubing **86**, and headlight **46**. Added to this embodiment is safety interlock **150** which consists of a solid member **152**, which when forced by contact with the subject animal skin, from a first, extended position, to a second retracted position in alignment with the proximal surface **22**, releases the needle mount to allow injection to occur. The safety interlock **150** is designed to prevent accidental injection of the human user of the system. Accidental injection of certain veterinary products can cause severe injury of the area accidentally injected. Mounted on hand-held injection device **40"'** is solid member **152,** a solid member preferably of plastic, which in its first position, extends at least as far as the tip of needle **56**. Solid member **152** is urged to a second position, pushed to the tip of the needle hub 57, as indicated by arrow in **Fig.11**, when the needle **56** and therefore the solid member **152** comes into contact with the body of the poultry or other animal. When solid member **152** is biased to the second position, it completes the electrical circuit and actuates the pump **100** which permits an injection to take place. This built-in safety device deters accidental, and severely injurious, self-injection. Needle **56** is replaceable. When needle guard solid member **152** reaches a second position, it actuates a Hall effect switch, <u>such as made by the Allegra</u>

Corp. of Worchester, Mass., internal of the hand-held injection device **[40, 40', 40"] 40"'** which controls administration. This Hall effect switch, shown in detail at **31** in **Fig. 13,** is wired in conjunction with the trigger **42** on the hand-held injection device **40"', 40""**, making it necessary for the trigger **42** to be depressed in order for the switch at the solid member **152** to work. This feature adds materially to the safety and reduced fatigue of the operator, as well as the speed of operation since the operator can depress the trigger **42** constantly allowing injection to occur automatically and as quickly as solid member **152** is depressed.

Paragraph beginning at line 2of page 12 has been amended as follows:

Fig. 7 is a perspective view of the interior of the control unit of **Fig. 6**. Electronic dosage control **130** uses a photo-optic unit to control the volume of medicament fluid pumped by pump **100**. Pump **100** drives shaft **134** which turns an encoder disc **132** that has slots that are placed at a calibrated distance from one another around the perimeter of circular encoder disc **132**. As the encoder disc **132** rotates in response to rotation of drive shaft **134**, the slots pass between an emitter and a receiver of a photo-optic sensor **138**. The encoder disc **132** passes through the sensor **138**. The sensor **138** "counts" the number of slots that pass between an emitter and receiver. The combination of the distance between the slots and the number of slots allowed to pass through the sensor **138** determines the amount of serum that is dispersed. This sensor **138** is wired into a circuit board **140** which includes a micro chip **142** which allows selection and control of the distance the fluid travels in pump **100**. This method is preferred because of the ease in changing doses and [*in view*] in view of the changing viscosities of the medicaments used. To change the dose, the user manipulates the function mode by pressing the "Function" key pad **108**, of control unit **110**. The current number of pulses will flash on the display **112**. The pulse count can then be changed by pressing the "UP" or "DOWN" key pad **106** until the correct number of pulses are shown. The press the "Function" keypad **108** to set the correct dose. The LCD display **112** will then stop flashing.

Paragraph beginning at line 12 of page 13 has been amended as follows:

Fig. 10 is a side view of a medicament mixing tube **190** with quick connect fluid connectors **196** at either end. Y-shaped coupling **198** brings together the two medicaments to mixing tube **190**. This tubing is inserted in the tubing somewhere between the pump **100** and any of the hand-held injection devices **40, 40', 40", 40"'** or **40""**. Injectible medicaments from two different sources may be mixed together by use of this mixing tube **190** prior to injection. This is used where the separate injectibles are compatible. In the case where they are not able to be mixed for some reason, the two injection hand-held injection device **40"** is used. In use, the mixing tube **190**, having a cylindrical barrel chamber **192** with a centrally positioned mixing member, double helix fins **194** shaped as two worm gears rotating in opposite directions, is provided enabling mixing together of two fluids for delivery to any of the hand-held injection devices **40, 40', 40", [or] 40"'or 40""**.